REMARKS

Claims 1-3 are pending in the present application. Independent claim 1, and claims 2 and 3 dependent directly or indirectly thereon, are directed to a method of determining a base sequence for nucleic acid.

In the Office Action, claims 1-3 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter.

It is alleged in the Office Action that step (f) (which recites "determining a base sequence of nucleic acid") is insufficient to provide statutory subject matter because it "may occur entirely within the processor of a computer without any indication to a practitioner that the computer is performing the method" and provides a result "without any physical transformation outside the computer" (Office Action of July 6, 2005 at page 2, last three lines and page 3, first two lines).

The rejection is respectfully traversed. Claims 1-3 recite subject matter that defines a concrete, tangible, and useful method. Specifically, the method is based on "detected data of electrophoresis of a fragment sample of nucleic acid," as recited in the first paragraph of claim 1. Further, the result of the claimed method, which is the determination of the "base sequence of nucleic acid," as recited in the last paragraph of claim 1, is a concrete, tangible, and useful result, whether it is displayed to the operator or stored in the computer, or further processed by a same or even transmitted to a different computer, for example.

Referring to MPEP 2106, Part IV, subpart B, as is done in the Office Action, it is submitted that this section of MPEP states explicitly that "Manipulation of Data Representing Physical Objects or Activities (Pre-Computer Process Activity)" is a "safe harbor" for satisfying the utility requirement. This section of MPEP refers to <u>Arrhythmia Research Technology Inc. v. Corazonix</u>

Corp., 22 USPQ2d 1032 (Fed. Cir. 1992), which held that method claims very similar to the

present claims were patentable subject matter under 35 U.S.C. 101 (the claims in US 4,422,459 at

issue in Arrhythmia were directed to a "method for analyzing electrocardiograph signals"

comprising steps of "converting… applying… determining… comparing").

Specifically, claim 1 at issue in Arrhythmia was:

> 1. A method for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high frequency energy in the late QRS signal, comprising the steps of:
> converting a series of QRS signals to time segments, each segment having a digital value equivalent to the analog value of said signals at said time;
> applying a portion of said time segments in reverse time order to high pass filter means;
> determining an arithmetic value of the amplitude of the output of said filter; and
> comparing said value with said predetermined level.

In Arrhythmia, compliance with 35 U.S.C. 101 patentability lies in the manipulation of

data representing physical objects or activity, not in further transformation outside a computer.

The Arrhythmia decision is cited with approval, discussed in details and used in MPEP as a typical

illustration of patentable subject matter. See MPEP 2106.IV.B.2(i) (section on "safe harbor"

patentable subject matter).

In contrast, in the decision In re Warmerdam, 31 USPQ2d at 1759 (Fed. Cir. 1994), to

which reference is also made in the Office Action, the claims of the application at issue in that case

were directed to a "method for generating a data structure which represents the shape of a physical

object" (to avoid collision between objects) and recited steps of "locating the medial axis of the

object" and "then creating a hierarchy of bubbles on the medial axis."

Specifically, claim 1 at issue in Warmerdam was:

> 1. A method for generating a data structure which represents the shape of [sic] physical object in a position and/or motion control machine as a hierarchy of bubbles, comprising the steps of:
> first locating the medial axis of the object and
> then creating a hierarchy of bubbles on the medial axis.

As discussed in MPEP 2106, IV.B.1 (section on non-patentable subject matter), both steps of claim 1 in Warmerdam "manipulate abstract ideas," i.e., the "medial axis" as well as the "bubble hierarchy" are not data resulting from "measurements of physical objects or activities" as in the safe harbor identified by MPEP 2106, IV.B.2(i). This is very different from the present claims, in which the method is "based on detected data of electrophoresis of a fragment sample of nucleic acid," a physical measurement, and results in "determining a base sequence of nucleic acid," a practical application having clearly "real world" value.

Reference is also made to the decision State Street Bank v. Signature, Inc. 47 USPQ2d 1596 (Fed. Cir. 1998), which followed Arrhythmia and Warmerdam. In State Street, the Federal Circuit held that a system for calculating share prices of mutual funds according to a "hub-and-spoke" method was patentable subject matter. The State Street court analyzed the means-plus-function system claims without requiring a step of further use of the calculated dollar amount:

> Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces "a useful, concrete and tangible result"—a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

State Street at 1601. In particular, in State Street, the Federal Circuit did not require that the final

share price be provided "outside the computer." The <u>State Street</u> decision also indicates that the analysis is analogous whether the claims are method or system claims.

Similarly, in the present application, the claimed method corresponds to the transformation of data, representing "detected data of electrophoresis" (instead of "dollar amounts" in <u>State Street</u>) through a series of mathematical calculations into a final "determined sequence" (instead of "share price" in <u>State Street</u>). Accordingly, in the presently claimed invention, the determination of the base sequence based on the electrophoresis data constitutes patentable subject matter without the need for a further step of "physical transformation outside the computer."

It is noted that, in the previous Office Action, it was indicated that the process lacked an "active step that recites creating the final base sequence for a nucleic acid," so that the claimed invention was limited to "manipulating data" and does not have a "practical application, i.e., something that is concrete, tangible and useful" (see Office Action of January 27, 2005 at page 5, last five lines). It is submitted that the presently claimed method which determines a base sequence of nucleic acid by connecting sequence-analyzed portions, as recited in present claim 1, has an appropriate practical application and satisfies the utility requirement.

In view of the above, it is submitted that the rejection should be withdrawn.

In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

In the event there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

In the event this paper is not considered to be timely filed, the Applicants hereby petition

for an appropriate extension of the response period. Please charge the fee for such extension and

any other fees which may be required to our Deposit Account No. 50-2866.

Respectfully submitted,

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